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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,979	04/09/2007	Stanley M. Lemon	265.00410101	9290

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581336
MINNEAPOLIS, MN 55458-1336

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,979	LEMON ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 41-46* is/are pending in the application.

4a) Of the above claim(s) *9-13 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14-36 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/06, 4/27/07, 5/7/07&6/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence letter*.

DETAILED ACTION

Election/Restrictions

1. In the previous restriction/election requirement, the claims were restricted into two groups. Group I includes claims 1-8, 14-36 and 41-43. The group II includes claims 9-13 and 44-46. The examiner apologizes for the typographic error in the previous office action.

2. Applicant's election without traverse of group I and species of an arginine mutation at amino acid position 2040 in the reply filed on Dec. 17, 2008 has been acknowledged.

3. Therefore, claims 1-8, 14-36 and 41-43 with species of an arginine mutation at amino acid position 2040. Claims 9-13 and 44-46 are withdrawn from consideration.

Sequence requirements

This application apparently contains several sequences as showed with defined sequence identified numbers (SEQ ID NOs) in Figs. 9-14, pages 17-19, page 23-25, 28-30, 56, and also a short sequence on page 21 line 11 that all are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with all of the sequences discussed above for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Specification

4. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes in **pages 18 and 29.** Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8, 14-35 and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-8, 14-35 and 41-43 are vague and indefinite in that the structure of the claimed polynucleotide is not define. First of all, claims 1, 14, 18, 26, 33 do not give any reference sequence from which the numeric numbers of the amino acids are counted. The genome of HCV are highly variable, and current HCV replicons are constructed in many different sizes as evidenced by Franciscus (HCV Genotype & Quasispecies published by HCSP, Feb. 2006, pages 1-3), and Blight et al. (J. Virol. 2003, Vol. 77, No. 5, pp. 3181-3190, see Fig. 1) or Ikeda et al. (J. Virol. 2002, Vol. 76, No. 6, pp. 2997-3006, see Figs. 1, 5, 8) or Kim et al. (BBRC 2001, Vol. 290, pp. 105-112, See Fig. 1) or Bartenschlager R. (US Patent No. 6/630,343B1, see columns 11-12). For example, Franciscus points out that HCV has at least six major genotypes or 11 genotypes different each from other by approximately 1/3, within the genotype are further divided into many subtypes different each from other by 20% as evidenced by Mellor et al. (J. Gene. Virol. 1995, Vol. 76, pp. 2493-2507), and quasispecies by less than about 2%. The overall genome sequences show 67-77% sequence similarity among all different HCV genomes as evidenced by Simmonds et al (J. Gene. Virol. 1994, Vol. 75, pp. 1053-1061). In addition, as a RNA virus, HCV also constantly changes/mutates its genome autonomously, which is estimated that the virus replicates- more than 1 trillion hepatitis C virions each day. During the replication process, the virus will make "bad" copies or error in the genetic make-up of the new replicated viruses. Therefore, a reference sequence is required to define what the structure of the claimed polynucleotide is. This is necessary for the examiner to examine and evaluate the novelty of the claimed HCV mutant. This rejection affects the dependent claims 2-8, 15-, 17, 19-25, 34-35 and 41-43.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. The invention of claims 1-2, 4-8 and 41 are directed to non-statutory subject matter. There is no recitation of isolation or synthesis in front of the claimed replication competent polynucleotide. Therefore, the claimed polynucleotide read on naturally occurring polynucleotide encoded by an HCV mutant, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language, "isolated or synthesized" to overcome this rejection. It is noted that a reasonable interpretation of the broadest scope of the claimed polynucleotide can be read on either naturally occurring DNA or RNA nucleotide that encodes the entire HCV infectious genome. The claim 41 may also read as a naturally occurring process of a HCV replication in a patient.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648

10.